

RE: National Quality Forum Patient Safety Measures: Complications Endorsement Maintenance

Is this comment on behalf of another person or organization?

- No
 Yes

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Comment #1: General comments on the draft report

On behalf of Pfizer, Inc., I am pleased to submit comments in response to the Patient Safety Measures: Complications Endorsement Maintenance Project. Pfizer is committed to advancing improvement in health and healthcare outcomes by developing innovative therapies and engaging in quality initiatives. As a research-based global leader in life sciences with extensive clinical expertise on a broad range of therapies, Pfizer possesses an acute awareness of the importance of prevention. We agree that the development, endorsement, and maintenance of performance measures are integral to patient-centered care and the delivery of high-quality healthcare services. We appreciate the opportunity to contribute to this project and look forward to continuing to work with NQF to improve patient care and outcomes. Pfizer specifically appreciates the opportunity to comment on measures #0022 and #0523.

NQF #0022. Measure name: Use of High Risk Medications in the Elderly. Steward: National Committee for Quality Assurance

Description: Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly in the measurement year. Percentage of patients 65 years of age and older who received at least two different drugs to be avoided in the elderly in the measurement year.

Numerator Statement: a: at least one prescription for any drug to be avoided in the elderly in the measurement year. b: At least two different drugs to be avoided in the elderly in the measurement year.

Denominator Statement: All patients ages 65 years and older as of December 31 of the measurement year.

Comment #2: General comment on measure #0022. "Use of High Risk Medications in the Elderly."

Pfizer urges NQF to defer endorsement of this measure. The current measure is obsolete, based on a list developed almost 10 years ago. As NQF notes, NCQA has stated that the American Geriatrics Society (AGS) is reviewing and updating the drug list. The AGS review and updating of what has been known as the "Beer's List" were published on March 1, 2012. While we appreciate NQF's efforts to align its endorsement activities with measure updates, we do not think it is appropriate to 1) endorse the current obsolete measure and 2) endorse an updated measure that has yet to be completed or reviewed.

Specifically, we have significant concerns about both the quality of evidence cited for estrogens and, in general, the appropriateness of translating this new list into a quality measure using the current specifications. While we agree with the goals stated by the authors of the AGS report – reducing medication related problems in older adult and improving health outcomes – we do not believe that the

new list (specifically, Table 2 in the article) can simply be translated into a quality measure penalizing health plans or physicians if patients utilize a particular medication on the list. The authors state that their goal is to improve care of older adults by reducing exposure to potentially inappropriate medications (PIMs), accomplished by the new Criteria's use as an educational tool and a quality measure. Yet, they acknowledge that these two uses are not always in agreement and, again, that the criteria are not meant to be used in a punitive manner. Clinicians must take into account multiple factors when deciding what medication is best for a particular patient. The evidence for a particular drug may vary among subpopulations or by certain patient characteristics. These factors contribute to the challenge of translating such a list into a clear-cut quality measure applied to the entire 65 and over population.

In addition, in comments to AGS on their draft report, we expressed concern about their treatment of estrogens, with or without progestin, and provided supporting evidence. We recommended that the review of "Estrogens with or without progestins" be split into a review of "estrogens alone" and a separate review of "estrogens with progestins," as the use of estrogen alone produces different results from its use in conjunction with progestins and these two therapeutic strategies are frequently studied and evaluated separately. Similarly, we suggested that AGS consider including recent evidence on the differential risk of endometrial cancer associated with estrogen alone therapy versus estrogen and progestin therapy. These distinctions are extremely important in the context of implementing the new Beers Criteria, and must be considered as the HRM measure is updated. In the AGS evidence tables 2 and 3 (released after the draft report was published), Pfizer finds a lack of alignment between the references listed and the original rationale for including estrogen on the HRM list. Namely, the references only discuss VTE, stroke, recurrent UTI, and urinary incontinence, whereas the original rationale was a noted increase in breast cancer risk in the estrogen with progestin group when compared to placebo. As such, Pfizer recommends NQF withhold continued endorsement of this measure until AGS has reconsidered the evidence base, and the measure has been appropriately revised.

[NQF #0523](#). Measure name: Pain Assessment Conducted. Steward: Centers for Medicare & Medicaid.

Description: Percentage of home health episodes of care in which the patient was assessed for pain, using a standardized pain assessment tool, at start/resumption of care.

Numerator Statement: Number of home health episodes of care in which the patient was assessed for pain, using a standardized pain assessment tool, at start/resumption of care.

Denominator Statement: Number of home health episodes of care ending during the reporting period, other than those covered by generic exclusions.

[Comment #3](#): General comment on measure #0523. "Pain Assessment Conducted."

Pfizer has concerns about NQF's proposal to remove endorsement of this measure, which is based on the rationale that evidence suggests a pain assessment alone does not lead to improved patient outcomes. Few studies have been conducted to directly assess the relationship between the use of pain assessment tools and patient outcomes. However, according to national practice guidelines and systematic reviews of pain management research, a thorough, comprehensive pain assessment is required for informed clinical decision-making and appropriate pain interventions.^{1,2,3,4} Underscoring

the importance of pain management, particularly for the home health population (to which NQF measure #0523 applies), the Centers for Medicare & Medicaid Services (CMS) requires home health agencies to report on patients' "Improvement in pain interfering with activity⁵." Without the use of proper pain assessment tools, patients may not be appropriately screened or managed for the severity of their pain. Chronic pain among older people often goes unreported and untreated or undertreated.⁶ The use of validated tools to assess pain may be especially valuable to home care clinicians, who are usually generalists, seeing patients with many different conditions, and who may refer to assessment tools for guidance. Given the prevalence of pain, and the need to appropriately diagnose and manage patients' pain symptoms, Pfizer encourages NQF to retain endorsement of this measure.

1. Wisconsin Medical Society Task Force on Pain Management. Guidelines for the assessment and management of chronic pain. *WMJ*. 2004;103(3):13-42.
2. American Geriatric Society (AGS). The management of persistent pain in older persons. *J Am Geriatr Soc*. Jun 2002;50(6 Suppl):S205-224.
3. Hadjistavropoulos T, Herr K, Turk DC, et al. An interdisciplinary expert consensus statement on assessment of pain in older persons. *Clin J Pain*. Jan 2007;23(1 Suppl):S1-43.
4. Institute for Clinical Systems Improvement (ICSI). Assessment and management of chronic pain. Bloomington, MN; 2007.
5. CMS. "List of Home Health Compare Quality Measures." <http://www.medicare.gov/HomeHealthCompare/Data/Measures/List.aspx>. Accessed 13 March 2012.
6. Wells N, et al. Improving the Quality of Care through Pain Assessment and Management (Chapter 17). In Hughes RG, ed. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville MD: AHRQ Publication; 2008.